SAMPLING AND ANALYSIS PLAN

for the

VASQUEZ BOULEVARD AND I-70 NPL SITE

PHASE III BIOMONITORING OF LEAD AND ARSENIC EXPOSURE

March 23, 2000

Prepared For: U.S. Environmental Protection Agency, Region 8 999 18th Street, Suite 500 Denver, CO 80202



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APPROVAL PAGE

This Project Plan for the Vasquez Boulevard & I-70 Site - Biomonitoring Sampling and Analysis Plan has been prepared at the request of the U.S. Environmental Protection Agency, Region 8, by ISSI Consulting Group, Inc. Study investigations and activities addressed in this Project Plan are approved without condition.

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VBI70 Biomonitoring Sampling and Analysis Plan

TABLE OF CONTENTS

| 1.0 | BAC | KGROUND AND STUDY OBJECTIVES | <u>1</u> |
|-----|------|--|---------------------------------------|
| 2.0 | DAT | A QUALITY OBJECTIVES | <u>2</u> |
| 3.0 | FIEL | D SAMPLING PLAN | <u>6</u> |
| | 3.1 | Identification of Potentially Impacted Residences | 6 |
| | 3.2 | Recruitment and Informed Consent for Biological Sampling | |
| | 3.3 | Collection of Biological Samples | |
| | | 3.3.1 Participant Questionnaires | - |
| | | 3.3.2 Sample Collection Methods | |
| | | 3.3.3 Sample Handling and Custody Requirements | |
| | | 3.3.4 Decontamination Procedures | |
| | 3.4 | Field Documentation | |
| | 3.5 | Sample Identification | |
| | 3.6 | Sample Preparation | |
| | 3.7 | Analytical Method Requirements | · · · · · · · · · · · · · · · · · · · |
| 4.0 | QUA | LITY ASSURANCE PROJECT PLAN | 11 |
| | 4.1 | Field Quality Control Samples | |
| | 4.2 | Detection and Quantitation Limits | |
| 5.0 | REFE | ERENCES | 14 |

FIGURES

| Figure 1 | Example Requisition Form |
|----------|--|
| Figure 2 | Instructions for Completing Requisition Form |
| Figure 3 | Data Collection Log |

ATTACHMENTS

Attachment 1

- 1. Blood Lead Sampling (SOP # VBI70-13)
- 2. Composite Hair Sampling for the Determination of Risk-Based Exposure to Total Arsenic (SOP # VBI70-14)
- 3. Urine Sampling for the Determination of Risk-Based Exposure to Arsenic (SOP # VBI70-15)
- 4. Preparation and Analysis Methods for Lead in Blood, Total Arsenic in Hair, and Inorganic Arsenic in Urine

Attachment 2

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- 1. Letter to Residents
- 2. Fact Sheet
- 3. Informed consent forms
- 4. Directions and instructions for providing samples
- 5. Example Requisition Form
- 6. Household Questionnaire
- 7. Child Questionnaire

TABLE OF ABBREVIATIONS

| ACGIH | American Conference of Governmental Industrial Hygienists |
|-------|---|
| CDC | Centers for Disease Control and Prevention |
| CFR | Code of Federal Regulations |
| COC | Chain of Custody |
| DQOs | Data Quality Objectives |
| MDL | Method Detection Limit |
| ppm | Parts Per Million |
| PQLs | Practical Quantitation Limits |
| QA/QC | Quality Assurance/Quality Control |
| SOPs | Standard Operating Procedures |
| UCL | Upper Confidence Limit |
| USEPA | United States Environmental Protection Agency |
| VBI70 | Vasquez Boulevard and Interstate 70 |

1.0 BACKGROUND AND STUDY OBJECTIVES

The Vasquez Boulevard and I-70 (VBI70) site is an area located in north-central Denver, Colorado. On July 22, 1999, USEPA added this area to the National Priority List (NPL) of Superfund sites, making it eligible to receive federal funds for investigation and cleanup.

The site is characterized mainly by residential neighborhoods, with scattered commercial/industrial properties. Investigations related to a nearby site (the Globe smelter) resulted in the observation that some residential properties in the VBI70 area have elevated levels of arsenic and/or lead in yard soils. EPA's initial studies at the site (referred to as Phase I and Phase II) revealed that contaminant levels (mainly arsenic) could be quite high in some properties, but that the spatial pattern was unpredictable (impacted properties often occur adjacent to unimpacted properties). A large-scale sampling plan referred to as Phase III Field Investigation is currently underway to obtain additional information on the pattern and extent of contamination (USEPA 1999a).

When elevated levels of arsenic and/or lead exist in soil, residents may be exposed by direct ingestion of the soil while working outdoors, or may be exposed indirectly by ingestion of indoor dust contaminated with soil. The hazards of such exposures can be estimated by using simple exposure and risk based models, but direct measurement of the actual level of exposure also provides useful information. Exposure to lead is generally evaluated by measurement of lead levels in blood. Exposure to arsenic may be evaluated either by measurement of arsenic in urine (this generally reflects recent exposures) or in hair (this generally reflects longer term exposures). Based on this, EPA established a program in conjunction with the Phase I and II studies to collect blood, hair and urine samples from individuals who resided at locations identified by EPA as being candidates for time-critical soil removal actions (USEPA 1998a,b; 1999b). Although limited, these biomonitoring data did not reveal any individuals with exposure levels that were clearly elevated or in a range of short-term health concern. Nevertheless, as Phase III sampling progresses, USEPA wishes to continue this voluntary biomonitoring program in order to promptly identify any individuals with exposures to lead and/or arsenic that are sufficiently high that short-term interventions may be needed to protect public health. Consequently, the objective of this component of the Phase III Field Investigation is to:

Collect biological samples from residents at properties known to contain elevated levels of lead and/or arsenic in order to identify individuals with exposures that are of potential short-term health concern.

2.0 DATA QUALITY OBJECTIVES

Data Quality Objectives (DQOs) are statements that define the type, quality, quantity, purpose and use of data to be collected. The design of a study is closely tied to the data quality objectives, which serve as the basis for important decisions regarding key design features such as the number and location of samples to be collected, the chemical analyses to be performed, etc.

USEPA has published a number of guidance documents on the DQO process (USEPA 1994, 1996, 1998c), and this sampling plan has been developed in accord with that guidance. In brief, the DQO process follows a seven-step procedure, as follows:

- 1. State the problem that the study is designed to address
- 2. Identify the decisions to be made with the data obtained
- 3. Identify the types of data inputs needed to make the decision
- 4. Define the bounds (in space and time) of the study
- 5. Define the decision rule which will be used to make decisions
- 6. Define the acceptable limits on decision errors
- 7. Optimize the design for obtaining data in an iterative fashion using information and DQOs identified in Steps 1-6

Following these seven steps helps ensure that the project plan is carefully thought out and that the data collected will provide sufficient information to support the key decisions which must be made. The following sections summarize the application of the DQO process to the design of the biomonitoring program.

Step 1. State the Problem

As the Phase III Field Investigation Project Plan is implemented, it is expected that some properties with elevated levels of lead and/or arsenic will be discovered. Limited biomonitoring data collected in association with the Phase I and Phase II investigations suggest that human exposures at properties with high levels of lead and/or arsenic may not be as high as predicted by traditional USEPA exposure models. However, these biomonitoring data are not sufficient to conclude that cases of immediate health concern might not occur at properties discovered during Phase III. Therefore, in order to be protective, USEPA seeks to obtain direct estimates of exposure to lead and arsenic in individuals who live at locations with high arsenic or lead levels in soil in order to judge what actions, if any, need be taken immediately.

Step 2. Identify the Decision to Be Made

The decision to be made is whether a short-term intervention is needed at a residence where elevated levels of lead and/or arsenic have been discovered. Note that a short-term intervention might take a number of forms, ranging from simple education of residents regarding protective steps they might take, to an actual removal of contaminated soils. Also note that a finding that no short-term intervention is needed at a property is <u>not</u> equivalent to a decision that no remedial (non-time-critical) action is needed. Indeed, it is expected that properties with soil levels high enough to warrant biomonitoring are likely candidates for remedial action. However, EPA will not make final remedial decisions until after collection of all site specific data and completion of the risk assessment.

Step 3. Identify Types of Input Needed

Two types of input are needed to reach this decision: 1) the location of properties with lead and/or arsenic levels in a range that might be of short-term health concern, and 2) the blood lead levels and the hair or urine arsenic levels of individuals residing at those locations. The location of properties with elevated levels of lead and/or arsenic in soil will be identified using the results of the Phase III residential yard soil investigation. Measurements of lead and arsenic in biological tissues will be obtained from this biomonitoring project.

Step 4. Define the Bounds of the Study

All residential properties located within the current boundaries of the VBI70 study area that have elevated levels of lead and/or arsenic in yard soil are candidates for biomonitoring. Soil levels which indicate the need for biomonitoring are summarized below.

Arsenic Levels that Warrant Biomonitoring

Calculations performed by USEPA (1998a) suggest that arsenic levels in the range of 400 - 900 ppm in yard soil might pose a short-term health risk to residents. Based on this information, biomonitoring during Phase III will focus on properties where arsenic levels exceed 400 ppm.

Lead Levels that Warrant Biomonitoring

As discussed in the same document (USEPA 1998a), lead levels above 2,000 ppm in yard soil might be of short-term health concern to residents. On this basis, a level of 2,000 ppm in soil is identified as the level where biomonitoring of blood lead should occur during Phase III to identify any cases of short-term concern.

Step 5. Define the Decision Rule

Arsenic

Arsenic is a normal component of the environment and is present at low levels in water, food and soil. Because of this, arsenic is expected to be present in low levels in the urine and the hair of all individuals. In urine, arsenic may occur in a number of different forms, including arsenite (As+3), arsenate (As+5), monomethyl arsenic (MMA), dimethyl arsenic (DMA), and several other complex organic arsenicals. Of these forms, As+3, As+5, MMA and DMA are considered to be the most relevant to assessing exposure to arsenic in soil, since the other more complex organic forms are only derived from the diet (mainly seafood). For the purposes of this SOP, the sum of As+3, As+5, MMA and DMA is referred to as "inorganic arsenic".

Data are not extensive on the normal range of arsenic in hair and urine of individuals with no special exposures to environmental arsenic, but data provided in ACGIH (1991), NRC (1999) and National Medical Services (Attachment 1) suggest the following values are likely to be representative of unexposed individuals:

| Tissue | Normal Range |
|-------------------|-----------------------------------|
| Hair | < 1 ug/g |
| Urine (inorganic) | < 20 ug/L < 20 ug/g creatinine |

Any individual with a hair measurement and urine measurements that fall within the normal range will not be considered as a candidate for any short-term intervention. Any individual with hair and/or arsenic levels that exceed the upper end of the normal range will be considered as a candidate for some sort of short-term intervention, with the nature of the intervention depending on the measured levels of arsenic in soil and/or dust in the house, and on the magnitude of the elevation in the biomonitoring parameter. Repeat testing of hair and/or urine will always be sought before any short-term actions or interventions are implemented.

Lead

The Centers for Disease Control and Prevention (CDC) has established recommended guidelines for the appropriate response to elevated blood lead levels detected in an individual (the levels are designed specifically for children, but may conservatively be used to evaluate adults as well). These guidelines are summarized below (CDC 1997):

| Blood Lead (ug/dL) | Recommended Response |
|--------------------|--|
| < 10 | No action; levels are not of concern |
| 10-14 | Provide information about ways to reduce lead exposure. Re-test within 3 months. |
| 15-19 | Provide information about ways to reduce lead exposure. Re-test within 2 months. If re-test result is the same or higher, perform full medical and environmental evaluation within 3 months. |
| 20-44 | Perform a full medical evaluation and environmental management assessment. |
| > 45 | Urgent medical follow-up and environmental management assessment is required. |

In accord with these guidelines, only locations where one or more individuals has a blood lead level exceeding 20 ug/dL will be considered as a candidate for a short-term intervention. Note that short-term harm is not expected at a blood lead level of 20 ug/dL, but this value is sufficiently high that prompt action to identify sources and reduce exposures is warranted. At locations where blood lead levels are less than 20 ug/dL but higher than 10 ug/dL, USEPA will provide the residents with information on ways in which lead exposure may be reduced until a final remedial decision is made.

Step 6. Identify Acceptable Limits on Decision Errors

Two types of potential decision error are associated with this project:

- 1: Intervening in a case where the risk of short term harm is actually minimal.
- 2: Failing to intervene in a case where the risks of short term harm are significant.

There is little or no disadvantage to making an error of the first type, except that this action might cause undue alarm or concern in the residents. However, with proper counseling and follow-up monitoring, this is not considered to be a serious problem. In contrast, an error of the second type is highly undesirable and low error rate must be sought. In this regard, there are two places where an error might occur:

1) Incorrectly classifying a property as being below the level where biomonitoring is needed, when the true level is actually above this level. When evaluating the need to recruit residents at a property to participate in the biomonitoring program, the estimate of

the concentration of arsenic in the yard will be based on the 95% UCL of the arithmetic mean concentration. In the case of lead, the decision will be based on the arithmetic mean. This is because the level of health concern for lead is calculated in such a way that at least 95% of all children exposed to that level will be protected. These two approaches ensure that essentially all properties where either arsenic and/or lead are above the level of potential short-term health concern will be identified for recruitment into the biomonitoring program.

Not intervening in the case of an individual whose exposure levels are of short-term health concern. With regard to the decision to implement short-term intervention or not, it is believed that each of the biomonitoring criteria established above are conservative (i.e., a small exceedence of the criterion is associated with only minimal risk of short-term health effect), so the probability of not intervening in a case in which there is an authentic and significant risk of short term harm is considered to be minimal. As an added precaution, any individuals who have biomonitoring results that approach but do not exceed the levels that are considered to be of short-term health concern will be strongly encouraged to provide one or more additional samples in order to characterize the true level of exposure more precisely.

Step 7. Optimize the Design

The basic design of this project may be refined as information becomes available on the number of properties that may warrant biomonitoring and on the arsenic and lead exposure levels observed in residents at those locations. Criteria for inclusion of a property in the biomonitoring study may be either increased or decreased as these data are received.

3.0 FIELD SAMPLING PLAN

Based on the data quality objectives outlined above, the key components of the field sampling plan needed to collect the necessary biomonitoring data are summarized below.

- Step 1: Identify properties that have arsenic and or lead levels in soil that are high enough to warrant biomonitoring of the residents at that property.
- Step 2: Contact residents at the selected properties and recruit their voluntary participation in the biomonitoring program.
- Step 3: Collect biological samples (hair, urine and blood) from all volunteers who participate in the program.
- Step 4: Measure arsenic levels in hair and urine and lead levels in blood, using methods

that are sufficiently sensitive and accurate to detect exceedences that are in a range of short-term health concern.

Step 5: Take appropriate action to intervene in any case where exposure levels exceed a criterion for risk of short term harm.

Specific tasks needed to perform each of these basic steps and achieve the objectives of the study are presented below.

3.1 Identification of Potentially Impacted Residences

As stated previously, residences will be selected for biomonitoring based on the results from the surficial yard soil portion of the Phase III field investigation. The criteria used to identify residences where biomonitoring will be recruited are as follows:

| Chemical | Criteria for Yard Soil Levels |
|----------|-------------------------------|
| Arsenic | 95% UCL of mean > 400 ppm |
| Lead | Mean > 2000 ppm |

ISSI will notify USEPA within one week whenever a property is identified that exceeds one or both of these criteria.

3.2 Recruitment and Informed Consent for Biological Sampling

As noted earlier, this biomonitoring program is strictly voluntary. Residents living in properties where lead and/or arsenic levels are of potential short-term health concern will be contacted by USEPA staff in a personal visit. Each will be informed of the reasons they are being contacted and provided a fact sheet that summarizes the basis for potential concern and explains the benefits of participating in the biomonitoring program.

All individuals who give consent to participate in the biomonitoring program will be given a package (see Attachment 2) which contains the following:

- An informed consent form for each individual. This form must be signed and
 provided to the clinic before any samples will be collected. For children under
 age 18, permission must be granted by their parent or guardian prior to sampling.
- A letter summarizing the reason that biomonitoring is believed to be desirable, and instructions for where and how to provide the biological samples. This

includes a map showing the location of the clinic, along with the phone number and a schedule of regular clinic hours. In addition, a fact sheet will be provided that shows how to reduce the risk of exposure to arsenic and lead.

Questionnaires to be completed by each participant

3.3 Collection of Biological Samples

3.3.1 Participant Questionnaires

Prior to sample collection, each participating resident will complete a household and/or child questionnaire. Information provided by the questionnaires may be useful in subsequent risk calculations. Household and child questionnaires are included in Attachment 2.

3.3.2 Sample Collection Methods

All biological samples will be collected in accord with the Standard Operating Procedures (SOPs) specific to each type of media:

Blood collection (SOP # ISSI-VBI70-13) Hair collection (SOP # ISSI-VBI70-14) Urine collection (SOP # ISSI-VBI70-15)

Each of these SOPs is provided in Attachment 1.

At least one sample of the appropriate biological media will be collected from each participant. Duplicate samples will be collected from willing participants in accord with the frequency specified in Section 4.0.

3.3.3 Sample Handling and Custody Requirements

Samples must be kept under strict chain-of-custody at all times. Samples will be locked and stored under chain-of-custody at the clinic until they are forwarded to the analytical laboratory for sample preparation and analysis. A sample is in an individual's custody if:

- It is in his/her possession
- It is in his/her view, after being in their possession
- It was in his/her possession and he/she either locked it or placed it in a sealed container to prevent tampering
- It is in a designated secure area

Chain-of-custody (COC) forms will be prepared for every sample collected immediately following collection of each sample. The Analysis Requisition form will serve as the COC form for all samples. An example requisition form is provided in Figure 1. Instructions for completing the form are provided in Figure 2.

Any samples in glass containers will be packaged for shipment using bubble wrap or equivalent packing materials. Containers carrying blood samples must be chilled using the blue ice packets provided by the analytical laboratory. Hair and urine samples will be transported using coolers, but temperature preservation is not required.

All samples shipped to the laboratory will be contained in a plastic cooler with packing material, if necessary, to prevent excessive agitation of the contents. All coolers will be securely taped closed, sealed with a minimum of two signed custody seals and labeled with a completed air bill prior to shipment.

3.3.4 Decontamination Procedures

Biological sampling equipment will not be re-used with one exception. Therefore, typically decontamination is not required. However the scissors used for clipping hair samples will be cleaned between samples using alcohol wipes. All personnel collecting biological samples will wear a new pair of disposable gloves for each sample collected. Proper disposal of all sampling equipment and materials is described in the appropriate SOPs (Attachment 1).

3.4 Field Documentation

When an individual visits the clinic to provide a sample of hair, urine, and/or blood, a requisition form and Data Collection Log must be completed to document the sample. Examples of the requisition form, Figure 1. Information contained in the requisition and the COC form includes the following:

- 1. Sample collection date and time
- 2. Name of the individual
- 3. Type(s) of sample (urine, blood or hair)
- 4. Chemical analyses requested on each sample (lead and/or arsenic)
- 5. Sample numbers assigned to each sample

An example of the Data Collection Log is provided in Figure 3. Information contained in the Data Collection Log includes the following:

1. Sample number

VBI70 Biomonitoring Sampling and Analysis Plan

- 2. Date collected
- 3. Time of collection for each medium (urine, blood or hair)
- 4. Technician's initials for each medium (urine, blood or hair)
- 5. Comments or notes of importance (if sample is a duplicate, or any deviations to SOP)

Copies of the requisition forms, COC forms, and the Data Collection Logs will be sent to USEPA's contractor (ISSI Consulting Group, Inc. [ISSI]) after each day of sampling. These copies will be stored in a three-ring binder book maintained by ISSI.

3.5 Sample Identification

Every biological and QC sample collected during this investigation will be identified with a unique sample identification number. Sample identification labels are found on the Analysis Requisition form. One label will be affixed to each biological sample container, so that the same sample ID is used for all samples collected from a participant. Duplicate samples will be identified by using an imaginary patient name to maintain anonymity at the analytical laboratory. The actual patient name must be identified in the Comments field of the Data Collection Log.

3.6 Sample Preparation

Blood

Blood samples will be prepared prior to analysis according to the procedure described in National Medical Services Method Number 6020 (Attachment 1).

Urine

Urine samples will be prepared prior to analysis according to the procedure described in National Medical Services Method Number 0468 (Attachment 1).

Hair

Hair samples will be prepared prior to analysis according to the following procedure.

Wash hands thoroughly with soap and water prior to handling hair sample. Put on a new pair of disposable latex gloves for each sample. Open sealed bag and remove vial cap. Remove half of the sample (about 0.2 g) and place in a new 15 x 100 mm disposable plastic petri dish. Wash with successive portions of 1.0% w/v sodium lauryl sulfate (or ammonium lauryl sulfate). After 30 minute contact with occasional agitation, the hair will be rinsed six times with deionized water and dried under laminar flow Class 100 air.

3.7 Analytical Method Requirements

The analytical method and project-required detection limits (PQLs) for each type of biological media being collected are provided in the tables below. Analytical method numbers refer to the numbering system used by National Medical Services, the analytical laboratory that will be used for this study.

Analytical Methods

| Analyte | Biological Sample Media | | | | | | | | |
|------------------------|-------------------------|------------|---------------------------|---------------|---------|---------------|--|--|--|
| | Hair | Method No. | Urine | Method No. | Blood | Method No. | | | |
| Arsenic (inorganic) | | | FIAS ^b | 0468 | | | | | |
| Arsenic (total) | GFASS * | 0460 | | | | | | | |
| Creatinine | | | Colorimetric ^c | 1348 | | | | | |
| Lead (total) | | | | | GFASS * | 6020 | | | |

^{*-} Graphite Furnace Atomic Absorption Spectroscopy

Project-Required Detection Limits

| Analyte | Biological Sample Type | | | | | | |
|---------------------|------------------------|---------|---------|--|--|--|--|
| | Hair | Urine | Blood | | | | |
| Arsenic (inorganic) | - | 10 ug/L | - | | | | |
| Arsenic (total) | 0.3 ug/g ^a | 10 ug/L | | | | | |
| Creatinine | | 5 mg/L | | | | | |
| Lead | | | 2 ug/dL | | | | |

^a The detection limit for arsenic in hair is a function of the mass of the hair available for analysis. A detection limit of 0.3 ug/g is the target, and this should be achievable for samples of 50 mg or more.

These methods are sufficiently accurate and sufficiently sensitive that any individual with exposure to lead or arsenic that is in a range of potential short-term health concern will be identified with high confidence.

^b - Flow Injection Atomic Spectroscopy

^e - Creatinine proportion is measured with a Monarch 2000 Auto-Analyzer

4.0 QUALITY ASSURANCE PROJECT PLAN

The complete Quality Assurance Project Plan (QAPP) for the VBI70 Phase III Field Investigation has been prepared in accordance with USEPA guidance documents. Quality assurance steps pertaining specifically to the biomonitoring program of Phase III are provided below.

4.1 Field Quality Control Samples

A number of quality control samples will be collected during this project to help assess the precision and accuracy of the data collected. These samples are described below.

<u>Field Duplicate</u>: Field duplicate samples are collected at the same time as the primary sample, and are submitted blind to the analytical laboratory to test both the precision of the analysis and the precision of sample collection. A minimum of 3 field duplicates will be sought from participating adults (but donation of a duplicate sample is voluntary). If the number of participants exceeds 50, field duplicate samples will be sought at a frequency of 5% of all samples collected (1 field duplicate per 20 investigation samples collected).

Field duplicates are defined as the following:

Blood:

A second vial of blood drawn from the same individual

Hair:

A second sample of hair collected from the same individual

Urine:

A second sample of urine provided by the same individual immediately

after collection of the first sample

Acceptance criteria for field duplicates is described in Section 4.8.1 of the Phase III Field Investigation Project Plan.

<u>Blind Standard</u>: The accuracy of an analytical method is evaluated by analyzing a sample medium fortified with a known concentration of target analytes that has been certified using the preparation and analysis method for that particular sample medium. The requirements for insertion of blind standards into the sample stream for each medium are presented below.

Blood

Blind standards for blood will be obtained from the University of Cincinnati. Two concentration levels will be used during this study, approximately 3 ug/dL and 15 ug/dL. A minimum of 3 blind standards (at each level) will be submitted to the analytical laboratory in a blind fashion. If the total number of blood samples exceeds 50, additional blind blood standards will be submitted

VBI70 Biomonitoring Sampling and Analysis Plan

to the analytical laboratory at a rate of about 5% (1 blind standard per 20 investigative samples). Results will be considered acceptable if the results for blind standards fall within the acceptance criteria established by the certifying laboratory approximately 95% of the time.

Urine

A minimum of 3 blind standards (at each of two levels) will be submitted to the analytical laboratory in a blind fashion. If the total number of urine samples exceeds 50, additional blind urine standards will be submitted at a rate of about 5% (1 blind standard per 20 investigative samples). Results will be considered acceptable if the results for blind standards fall within the acceptance criteria established by the certifying laboratory approximately 95% of the time.

Hair

A source to obtain blind standards for arsenic in hair was not located. Therefore, analytical accuracy for hair analysis will be assessed by reviewing matrix spike analyses performed by the laboratory.

4.2 Detection and Quantitation Limits

The Method Detection Limit (MDL) is defined as the concentration of a substance that can be recognized as being greater than zero with 99% confidence. Typically, the MDL is defined as 3-times the standard deviation of seven replicate analyses of a site sample containing a low but detectable level of the analyte. The Practical Quantitation Limit (PQL) is generally defined as 10-times the standard deviation determined from the MDL study (or often described as 3 times the MDL). A MDL study must be performed for each method utilized in the study in accord with guidance outlined in the 40 CFR Part 136, Appendix B. Results that are below the PQL, but above the MDL will be qualified with a 'B' flag and reported as estimated results.

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FIGURES

Figure 1 10N

| | ANALYSIS REQUISITI |
|------------|--|
| 19 | **Mational Medical Services, Inc. 3701 Welsh Rd. © P.O. Box 433A Willow Grove, Pennsylvania 19090-0437 (215) 657-4900 (800) 522-6671 FAX: (215) 657-2972 |
| . <u>:</u> | Biomonitoring for Environmental/Occupational Exposure & Criminalistics Forensic Toxicology & Therapeutic Drug Monitoring |
| | ● CLIENT TO FILL IN SHADED AREAS ONLY ● |

ECIMENT

RILEASE PRINTEPATIENTE PO NEORMATION FOR AFRIX. PO: L'ABELL BELL

CONTROL NO.

519924



ACCOUNT NO.

30795

ACCOUNT NAME/ADDRESS

ISSI CONSULTING GROUP 999 18TH AVE. **DENVER, CO 80202** ·

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|)' | ARSENIC (SPECIATED) | 1864 | | DRUG SCREEN (BLOOD OR SERUM) | 3226 | | OLANZAPINE . | | |
| 3460 | ARSENIC (TOTAL) | 8489 | | FENTANYL + METAB. (FORENSIC) | 8660 | 製 | OPIATES - UNCONJ. (ACTIVE) W/GC/MS | | |
|) | BENZENE (BLOOD) | 9315 | | FLUNITRAZEPAM & METABOLITE | 3360 | 類 | PAROXETINE | NING TARELOW | V GROVE 19090-0437 |
|) | BENZODIAZEPINES W/GC/MS | 2124 | | FLUVOXAMINE (LUVOX®) | 3370 | | PCB's (POLYCHLORINATED BIPHENYLS) | | V GNOVE 19090-0437 |
|)620 | BENZTROPINE (COGENTIN®) | 2134 | | FORMIC ACID . | 3445 | | PESTICIDE/INSECTICIDE SCREEN* | CONTROL NUMBER | 519924 |
|) 3 | BUPROPION (WELLBUTRIN®)* | 2143 | | GABAPENTIN | 3784 | 製 | POTASSIUM | ! | 010027 |
|)t; | BUSPIRONE (BUSPAR®) | 2152 | * | GHB (GAMMA-HYDROXYBUTYRIC ACID) | 3976 | 鑾 | PROPAFENONE | | |
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| | CADMIUM PANEL (OSHA) | 2390 | | IBUPROFEN | 4180 | 壁 | SELENIUM | NMS - WILLOW | GROVE 19090-0437 |
| | CANNABINOIDS (THC) W/ GC/MS | 2416 | | INHALANTS - URINE METABS. | 4195 | | SERTRALINE | CONTROL | |
| 970 | CARBAMAZEPINE + METABOLITE | 2440 | | ISONIAZID*† | 4205 | 310 | SINEMET®* - | NUMBER | 519924 |
| 071 | CARBAMAZEPINE + METAB FREE | 2484 | * | LAMOTRIGINE (LAMICTAL®) | 0641 | | SOTALOL _ | | 10 10 10 10 10 10 10 10 10 10 10 10 10 1 |
| ξ Ξ | CARBAMAZEPINE + METAB FREE/BOUND | 2492 | | LEAD - SERUM | 4260 | | SULFONYLUREA HYPOGLYCEMICS | | |
| 250 | CHOLINESTERASE (RBC OR PLASMA) | 6020 | X | LEAD IN BLOOD | 4305 | 黨 | TACRINE (COGNEX®) | | HR 1814 IE IS HELT IN SI |
| 261 | CHROMIUM | 2541 | 3 | LSD SCREENT | 4370 | 鑓 | THALLIUM | NMS - WILLOW | GROVE 19090-0437 |
| 2 | 4 | 2551 | | MAGNESIUM | 4395 | R. | TICLOPIDINE (TICLID®)* | CONTROL NUMBER | E10024 |
| 277 | CLONIDINE | 2570 | | MANGANESE | 4518 | | TOPIRAMATE (SERUM OR PLASMA) | (4014:02:1 | 519924 |
| 287 | CLOZAPINE + METABOLITE | 2670 | | MERCURY | 4660 | 73 | TRIFLUOPERAZINE (STELAZINE®) | | |
| 3 | COCAINE + METAB. W/ GC/MS | 6153 | 量 | METALS PANEL - RBC's | 4769 | | VENLAFAXINE + METABOLITE (EFFEXOR®) | | |
| | COPPER | 2661 | | METALS/METALLOIDS I (BLOOD) | 4774 | | VIGABATRIN | NMS - WILLOW | GROVE 19090-0437 |
| 153 | COTININE - URINE | 3020 | | METHYLPHENIDATE (RITALIN®)* | 4800 | | WARFARIN | MAIO - MILLOW | |
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| IF ANALYSIS DOES NOT APPEAR ABOVE, PLEASE WRITE TEST NAME/NUMBER IN SPACE PROVIDED BELOW. | |
|---|----|
| =+ #1348: Creatinine in Urine | |
| + # C460: Hair Segmentation required | le |

4 segments: 0-1 cm 1-3 cm

3-5 cm

BRV

BRPC

(if length of sample allows)

| RN | lote | | | | | 1 | Cmt | | | |
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VERIFICATION:

FIGURE 2: INSTRUCTIONS FOR COMPLETING CLINICAL ANALYSIS REQUISITION FORM

NMS Analysis Requisition are multi-copy perforated forms that include unique specimen identification Control Number labels (see Figure 1 for example). When completing this form, please press firmly to ensure information is transferred to each page.

The following information must be provided for each participant:

- 1. Name Print participant's name clearly, last name first
- 2. Age
- 3. Sex
- 4. Forensic Leave blank
- 5. Stat Leave blank
- 6. Return Specimen Leave blank
- 7. Specimen type All requisition forms should have checkmarks in the boxes for blood, urine, and hair samples when samples have been collected
- 8. Specimen Collection The following information is requested:
 - Date of specimen collection
 - Time (in military time) of specimen collection

For urine samples:

- Box marked "Random" should be checked, and "Timed Sample" left unchecked
- Elapsed time shouldn't be any
- Volume estimated urine sample volume, in ml
- 10. Indicate the requested analytical method number in the space provided (as indicated in the example) by marking an "X" in the following boxes:
 - 0460 Arsenic Hair (total)
 - 0468 Arsenic Urine (inorganic)
 - 6020 Lead in Blood
 - 1348 Creatinine in Urine
- 11. In the space provided in the lower left-hand corner, the following test informatrion must be included:
 - Test #1348: Creatinine in Urine
 - Test #0460: Hair segmentation required: 4 segments (if length of sample allows): 0 1cm; 1 3cm; 3 5cm; 5 7cm

Remove the pressure sensitive Control Number labels from the top copy of the Analysis Requisition and securely apply one label to each specimen submitted per requisition.

Remove the last copy of the Analysis Requisition and place in the Field Notebook behind the Data Collection Log.

Figure 3

Data Collection Log

| | Date | ŀ | lair | BI | ood | | Urine Comments | |
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ATTACHMENT 1

SOPs for COLLECTION OF BIOLOGICAL SAMPLES

SOP Title

- 1. Blood Lead Sampling (SOP # VBI70-13)
- 2. Composite Hair Sampling for the Determination of Risk-Based Exposure to Total Arsenic (SOP # VBI70-14)
- 3. Urine Sampling for the Determination of Risk-Based Exposure to Arsenic (SOP # VBI70-15)
- 4. Preparation and Analysis Methods for Lead in Blood, Total Arsenic in Hair, and Inorganic Arsenic in Urine

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Blood Lead Sampling (SOP # VBI70-13)

| Date: November 30, 19 | 999 (Rev. # 0) | SOP No. <u>ISSI-VBI70- 13</u> |
|------------------------|--|-------------------------------|
| Title: BLOOD LE. | AD SAMPLING | |
| APPROVALS: | · · | |
| AuthorI | SSI Consulting Group, Inc | Date: November 30, 1999 |
| | ardized method for the collection of blood risk-based exposure to lead. Protocols fo are provided. | |
| Received by QA Unit: | | |
| REVIEWS: | | |
| TEAM MEMBER | SIGNATURE/TITLE | DATE |
| EPA Region 8 | Bout Since Ferry | <u>= 4/14/00</u> |
| ISSI Consulting Group, | Inc. WS Bratten | 2/15/00 |
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| Revision Date | Reason for Rev | ision |
| | | |

Technical Standard Operating Procedures ISSI Consulting Group, Inc. Contract No. N00174-99-D-003

SOP No. <u>ISSI-VB170-13</u> Revision No.: 0 Date: 11/1999

Page 1 of 7

BLOOD LEAD SAMPLING

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to provide a standardized method for collecting blood for subsequent determination of exposure to lead. Blood samples from subjects recruited into the study will be collected at a neighborhood clinic by study personnel. Trained phlebotomists will collect these samples using venipuncture collection techniques. All personnel involved with the blood collection will be trained in this procedure. This SOP describes the equipment and operations used for collecting blood, using a procedure that will produce data that can be used to support risk evaluations. Site-specific deviations from the procedures outlined in this document must be approved by the USEPA Region 8 Remedial Project Manager, or Regional Toxicologist prior to initiation of the sampling activity.

2.0 RESPONSIBILITIES

The contractor who is responsible for overseeing the biomonitoring activities (ISSI) will be responsible for checking all work performed and verifying that the work satisfies the specific tasks outlined by this SOP and the Project Plan. It is also the responsibility of the contractor to communicate the need for any deviations from this SOP with the appropriate USEPA Region 8 personnel (Remedial Project Manager, or Regional Toxicologist). It is the responsibility of the subcontractor collecting the sample (Concentra) to communicate with all personnel regarding specific collection objectives and to communicate with ISSI regarding any anticipated situations that require deviation from this SOP.

All personnel performing biological sampling are responsible for adhering to the applicable tasks outlined in this procedure while collecting samples.

3.0 EQUIPMENT

- <u>Collection containers</u> certified lead-free Vacutainer tubes preserved with EDTA
- <u>Vacutainer winged collection set (butterfly)</u>
- <u>Gloves</u> Disposable, latex, powderless.
- Tube holder
- Syringe
- Alcohol pads
- Gauze sponges (2 x 2s)
- Band-aids
- Tourniquet
- Analysis Requisition forms will be provided by ISSI
- Consent form will be provided by ISSI
- <u>Field notebook</u> a three-ring binder book that will store necessary forms used to record and track samples collected as part of the VBI70 biomonitoring program.

BLOOD LEAD SAMPLING

Binders will contain sample requisition forms and Data Collection Logsheets and Analysis Requisition forms.

4.0 METHOD SUMMARY

Every effort must be made to avoid lead contamination. The skin will be thoroughly cleansed prior to sample collection. Caps will never be removed from Vacutainer tubes prior to, or during sampling. Samples will be clearly marked with the patient's name, date of collection, and patient's social security number.

5.0 COLLECTION OF BLOOD SAMPLES

5.1 Venipuncture

A new pair of disposable gloves are to be worn for each new patient.

Venipuncture samples will be drawn using a 23 gauge butterfly apparatus attached to a tube holder or a syringe. Prior to collection, all necessary supplies and equipment should be laid out on a clean tray. Wash hands well with soap and water, and then put on a new pair of gloves. Locate the puncture site, and apply a new alcohol wipe to the site. Hold the puncture site by pinching either end of the alcohol wipe so that only the alcohol wipe is touching the patient's skin. Wipe the area in a circular motion beginning with a narrow radius and moving outward so as not to cross over the area that has already been cleaned. Repeat this action with a new alcohol wipe to remove any lead particles adhering to the skin.

Locate the vein and apply the tourniquet. Fix the vein by pressing down on the vein about 1 inch below the proposed point of entry, and pull the skin taut. Approach the vein from the same direction the vein is running, holding the sterilized needle at a 15-degree angle with the patient's arm. Push the needle, bevel side facing up, quickly and deliberately into the vein. If the needle is in the vein, blood will flow freely through the butterfly tubing and into the tube. If no blood enters the tube, probe for the vein carefully (avoid hematoma formation) until entry is indicated by blood flowing into the tube. Fill the Vacutainer tube with at least 1.5 - 2cc of blood. When sampling is complete, remove the tourniquet and then extract the needle from the vein. With the arm elevated, allow the patient to hold a clean gauze sponge onto the puncture wound, until the wound has clotted. Secure with a band-aid.

If the patient is less than 1 year old or is very small, a syringe attached to the butterfly tubing should be used instead of the Vacutainer tube. This will avoid collapsing the veins of very small children. Once the needle is in the vein and blood can be seen in the butterfly tubing, aspirate the syringe. Gently fill the syringe collecting approximately 2 ml of blood. Remove the tourniquet during this process and then extract the needle from the vein. Allow the patient or a parent to hold a clean gauze sponge onto the puncture wound. Fill the Vacutainer tube by puncturing the top and *gently* releasing blood into the tube.

BLOOD LEAD SAMPLING

After collection, immediately invert the Vacutainer tube, and gently repeat this process several times to mix the sample with the EDTA preservative. Remove disposable gloves and dispose of these and all other blood collection equipment in an appropriate container designated for sharps or biological waste. Wash hands.

6.0 SAMPLE CONTAINERS AND LABELING

Following the procedures outlined in Section 5.0, samples will be collected directly into sample containers (Vacutainer tubes) and labeled with a unique sample identification number. Each sample must have an identification number affixed to the collection tube, and also attached to the Analysis Requisition form.

7.0 SITE CLEAN-UP

Dispose of needles in a container designated for sharps. Blood saturated materials must be disposed of in a container designated for biological waste.

8.0 FIELD QUALITY ASSURANCE/QUALITY CONTROL

Adherence to quality assurance/quality control (QA/QC) procedures is an important part of field sample collection. Field QA/QC procedures include documentation requirements and preparation of field QC samples.

8.1 Field Quality Control Samples

The following quality control samples will be collected during this project to help assess the precision and accuracy of the data collected.

Field Duplicate: Field duplicate samples are collected at the same time as the primary sample, and are submitted blind to the analytical laboratory to test both the precision of the analysis and the precision of sample collection. In this case, the field duplicate sample is a second sample of blood drawn from the same individual, by fitting a second tube onto the butterfly or syringe immediately after filling the first tube. A minimum of 3 field duplicates will be collected from participating adults. If the number of samples exceeds 50, field duplicate samples will be collected at a frequency of 5% of all samples collected (1 field duplicate per 20 investigation samples collected). Field duplicate samples are submitted in a blind fashion to the analytical laboratory. In order to maintain anonymity, field duplicates will be labeled with 'dummy' patient names and inserted into the sample stream. A list of 'dummy' patient names is provided in Attachment 2. Direction for the selection and submission of field duplicates will be the responsibility of ISSI.

Blind Standard: The accuracy of an analytical method is evaluated by analyzing a sample

BLOOD LEAD SAMPLING

medium fortified with a known concentration of target analytes that has been certified using the preparation and analysis method for that particular sample medium. Blind standards will be inserted into the sample stream using 'dummy' patient names to maintain the anonymity of the sample. A minimum of 3 blind standards at 2 lead concentrations will be inserted into the sample stream by ISSI.

8.2 Field documentation

A field notebook should be maintained by the personnel collecting blood samples. The field notebook is a three-ring binder that contains a Data Collection Log and the Analysis Requisition form for each patient. All entries in the field logbook must be signed and dated by the person recording the information.

The following information will be included on the Data Collection Log;

- date of collection
- time of collection
- name of sampling technician
- patient name
- sample identification number
- descriptions of any deviations to this SOP and the reason for the deviation

An example of the Analysis Requisition form and the Data Collection Log is provided in Attachment 1.

9.0 DECONTAMINATION

Biological sampling equipment will not be re-used. All sampling equipment must be disposed in appropriate containers designated for biological waste.

10.0 GLOSSARY

<u>Project Plan</u> - The written document that spells out the detailed site-specific procedures to be followed by the Project Leader and the Clinic Personnel.

11.0 REFERENCES

Bornschein, 1989. 1989 Midvale Community Blood Lead Study Protocols.

MDPH (Massachusetts Department of Public Health). Procedure for obtaining finger stick blood samples. Jamaica Plain (MA): MDPH, Childhood Lead Poisoning Program, 1990.

MHD (Milwaukee Health Department). Generalized procedure finger stick blood (hematocrit and/or lead test). Milwaukee: MHD, 1988.

TECHNICAL STANDARD OPERATING PROCEDURE BLOOD LEAD SAMPLING

ATTACHMENT 1

| ANALYS | IS RI | EQUISITION | | | |
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| Logbook Page Reviewed By: | Date: |
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TECHNICAL STANDARD OPERATING PROCEDURE BLOOD LEAD SAMPLING

ATTACHMENT 2

Patient Names to be Used for Blind Quality Control Samples

| # | Social Security | Name |
|---|--|---|
| | 527-55-3942 | Kyle Anderson |
| | 304-77-9165 | Harold Brame |
| | 636-73-6452 | Rajeev Chaula |
| | 746-01-4495 | Polly Davis |
| | 430-67-2533 | Craig Ensley |
| | 271-85-9411 | Alessandro Fortin |
| | 401-77-1802 | Abel Glardon |
| | 629-54-4980 | Floyd Harrison |
| | 520-11-9257 | Robert Hendrickson |
| | 410-56-3309 | Andrew Iverson |
| | 461-98-0835 | Diana Isham |
| | 529-57-0640 | Sarah Jennigan |
| | 528-62-8117 | Raymond Jones |
| | 825-24-1955 | Frank Knotts |
| | 539-30-9609 | James Kutsko |
| | 674-78-0370 | Lonnie Labriola |
| | 665-07-7231 | Brian Lucero |
| | 455-14-8527 | Kristine Molinari |
| | 347-53-7037 | Anita Marshall |
| | 936-83-5385 | Albert Musser |
| | 495-90-0510 | Amy Noel |
| | 662-88-3825 | Etsuko Nishimura |
| | 652-97-6791 | Andrew Ochoa |
| | 520-92-0424 | Carol Ottmer |
| | 261-14-4322 | Beulah Peek |
| | 566-59-2501 | Ardith Pritchard |
| | 510-50-6497 | Roy Quinlan |
| | 427-74-0676 | Agustin Quintero |
| ı | 512-26-3959 | Ace Ratcliff |
| | 450-42-3918 | Aaron Roybal |
| ١ | 603-31-3864 | Arturo Sigala |
| | 548-30-5794 | Karl Steinbeck |
| | 599-10-4556 | Anita Sanchez |
| | 416-61-3547 | Kurt Swingle |
| - | 334-30-4184 | Lao Tizer |
| - | 605-63-4911 | Carrie Trupiano |
| - | 655-91-6413 | |
| - | 524-52-0927 | Chris Utz |
| | 520-97-3678 | Benito Valdez |
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| ı | 608-93-5468 | |
| - | *************************************** | Peter Wolfe |
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| | 655-91-6413 524-52-0927 520-97-3678 527-21-9696 | Murray Unell Chris Utz Benito Valdez Alvin Voight Barbara Waldinger |

TECHNICAL STANDARD OPERATING PROCEDURE HAIR SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

| Date: March 16, 2000 (Rev. #1) | SOP No. <u>ISSI-VBI70- 14</u> |
|--|------------------------------------|
| Title: HAIR COLLECTION FOR THE DETERMINAT | ION OF EXPOSURE TO ARSENIC |
| APPROVALS: | |
| AuthorISSI Consulting Gro | oup, Inc Date: November 30, 1999 |
| SYNOPSIS: A standardized method for the collection are subsequent analysis of arsenic is provided. | nd preparation of hair samples for |
| Received by QA Unit: | |
| REVIEWS: | |
| TEAM MEMBER SIGNATURE/TITE | LE DATE |
| EPA Region 8 ISSI Consulting Group, Inc. | RPM 4/1/00 4/18/00 |

| Revision Date | Reason for Revision Added procedure for instructing lab to segment hair samples longer than 2 inches. | | | |
|----------------|--|--|--|--|
| March 16, 2000 | | | | |
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HAIR SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to provide a standardized method to be implemented by employees of EPA Region VIII or contractors and subcontractors supporting Region VIII projects and tasks. This SOP describes the equipment and operations used to collect samples of hair for subsequent analysis of arsenic. Site-specific deviations from the procedures presented in this document must be approved by the Project Manager or Regional Toxicologist prior to initiation of the sampling activity.

2.0 RESPONSIBILITIES

The contractor who is responsible for overseeing the biomonitoring activities (ISSI) will be responsible for checking all work performed and verifying that the work satisfies the specific tasks outlined by this SOP and the Project Plan. It is also the responsibility of the contractor to communicate the need for any deviations from this SOP with the appropriate USEPA Region 8 personnel (Remedial Project Manager, or Regional Toxicologist). It is the responsibility of the subcontractor collecting the sample (Concentra) to communicate with all personnel regarding specific collection objectives and to communicate with ISSI regarding any anticipated situations that require deviation from this SOP.

All personnel performing biological sampling are responsible for adhering to the applicable tasks outlined in this procedure while collecting samples.

3.0 EQUIPMENT

- alcohol wipes
- disposable latex gloves
- stainless steel scissors
- Protectikit[™] Hair Specimen Collection Kit will be provided by ISSI
- sealable plastic bags
- permanent marker or ink pen
- trash bag
- tape measure or ruler
- Analysis Requisition forms will be provided by ISSI
- Consent forms will be provided by ISSI
- Field Notebook three-ring binder book used to store necessary forms that record and track samples collected as part of the VBI70 biomonitoring program. Binders will contain Data Collection Logsheets, and Analysis Requisition forms

HAIR SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

4.0 COLLECTION OF HAIR SAMPLES

Hair is collected by cutting a small portion at the nape of the neck, using the procedure outlined below.

4.1 For hair samples less than two inches:

Wash hands thoroughly with soap and water prior to taking a hair sample. Put on a new pair of disposable gloves. Clean the scissors blades with a new alcohol wipe and allow to air dry. Tightly twist a ¼ inch diameter bundle of hair (approximately as thick as a pencil) from the nape of the neck. This is approximately 0.5 g. Carefully snip the hair as close to the scalp as possible. Use a tape measure or pocket ruler to measure the length of hair cut. Remove the lid from the small cardboard sampling box marked "Collection Method B", and fill with loosely packed hair. Replace the lid, seal with the evidence seal included in each collection kit, and place the box into the larger Hair Specimen Collection Kit box. Affix a sample identification number to the upper right-hand corner of the collection kit, and to the Analysis Requisition form. Place the box in a plastic bag, seal the bag, and label the measured hair length with a permanent marker or ink pen. (Samples do not need to be refrigerated.) Use a new alcohol wipe to clean the scissor blades. After the scissors have been cleaned, dispose of the alcohol wipes and the disposable gloves.

<u>Limited Sample</u>: A minimum of 0.5g must be obtained for analysis. If the hair is too short and an 0.5g sample cannot be obtained in one bundle, several smaller bundles can be collected as described above, and placed into a single sample container.

4.2 For hair samples longer than two inches:

Wash hands thoroughly with soap and water prior to taking hair sample. Put on a new pair of disposable gloves. Clean the scissor blades with a new alcohol wipe, and allow to air dry. Tightly twist a ¼ inch diameter (approximately as thick as a pencil) bundle of hair from the nape of the neck. While holding the tightly twisted hair in one hand, spread open the tygon hair collection tube with the other hand, then enclose the hair in the collection tube as close to the scalp as possible (refer to the figures included in each hair collection kit). Carefully snip the hair as close to the scalp as possible. Use a tape measure or pocket ruler to measure the length of hair cut. Wrap the tygon tubing around the root end of the hair bundle, and mount the hair sample on the collection board marked "Collection Method A". Seal the Hair Specimen Collection kit with the evidence seals included in each Protectikit™ box. Affix a sample identification number to the upper right-hand corner of the box, and to the Analysis Requisition form. Place the collection kit into a plastic bag, seal the bag and label the measured hair length with a permanent marker or ink pen. (Samples do not need to be refrigerated.). Use another new alcohol wipe to clean the scissor blades. After the scissors have been cleaned, dispose of the alcohol wipes and the disposable gloves in an appropriate container.

Technical Standard Operating Procedures ISSI Consulting Group, Inc. Contract No. N00174-99-D-003

SOP No. <u>ISSI-VBI70-14</u> Revision No.: 1 Date: 3/2000

HAIR SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

5.0 SAMPLE CONTAINERS AND LABELING

Following the procedures outlined in Section 4.0, samples will be collected directly into sample containers and labeled with a unique sample identification number. Each sample must have a sample identification number affixed to the collection container, and also attached to the Analysis Requisition form.

For hair samples longer than two inches - Segmentation instructions must be included on each Analysis Requisition Form. In the lower left-hand corner of the form, provide the following directions to the lab (see Attachment 1):

Hair segmentation required: 4 segment analysis as follows: 0-1cm; 1-3 cm; 3-5 cm; 5-7 cm (if length of sample allows).

6.0 SITE CLEAN-UP

Dispose of all sampling equipment (used gloves, wipes) in a trash bag.

7.0 FIELD QUALITY ASSURANCE/QUALITY CONTROL

Adherence to quality assurance/quality control (QA/QC) procedures is an important part of field sample collection. Field QA/QC procedures include documentation requirements and preparation of field QC samples.

7.1 Field Quality Control Samples

The following quality control samples will be collected during this project to help assess the precision and accuracy of the data collected. All quality control samples will be inserted into the sample stream by ISSI.

<u>Field Duplicate</u>: Field duplicate samples are collected at the same time as the primary sample, and are submitted blind to the analytical laboratory to test both the precision of the analysis and the precision of sample collection. In this case, the field duplicate sample is a second sample of hair collected from the same individual. Because all hair sampling is voluntary, duplicate samples will be collected only when authorization is explicitly given A minimum of 3 field duplicates will be sought from adult participants. If the number of samples exceeds 50, field duplicate samples will be sought at a frequency of 5% of all samples collected (1 field duplicate per 20 investigation samples collected). Field duplicate samples are submitted in a blind fashion to the analytical laboratory. In order to maintain anonymity, field duplicates will be labeled with 'dummy' patient names and inserted into the sample stream. A list of 'dummy' patient names is provided in Attachment 2. Direction for the selection and submission of field duplicates will be the responsibility of ISSI.

Technical Standard Operating Procedures ISSI Consulting Group, Inc. Contract No. N00174-99-D-003

SOP No. <u>ISSI-VBI70-14</u> Revision No.: 1 Date: 3/2000

HAIR SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

Blind Standard: No source of certified or otherwise standardized samples of hair for arsenic analysis could be located. Therefore, no blind standards of hair can be incorporated into the QA program..

7.2 Field documentation

A field notebook should be maintained by the personnel collecting hair samples. The field notebook is a three-ring binder that contains a Data Collection Log and the Analysis Requisition form for each patient. All entries in the field logbook must be signed and dated by the person recording the information.

The following information will be included on the Data Collection Log:

- date of collection
- time of collection
- name of sampling technician
- patient name
- patient's social security number
- descriptions of any deviations to this SOP and the reason for the deviation

An example of the Analysis Requisition form and the Data Collection Log is provided in Attachment 1.

8.0 DECONTAMINATION

Stainless steel scissors will be decontaminated using alcohol wipes, as described in Section 4.1 and 4.2. All other sampling equipment is not reusable and must be disposed in an appropriate container(s).

9.0 GLOSSARY

<u>Project Plan</u> - The written document that spells out the detailed site-specific procedures to be followed by the Project Leader and the clinic personnel.

10.0 REFERENCES

Paschal, D.C., E.S. DiPietro, D.L. Phillips and E.W. Gunter. 1989. Age Dependence of Metals in Hair in a Selected U.S. Population. Environmental Research. 48: 17-28.

USEPA. 1978. Human Scalp Hair: An Environmental Exposure Index for Trace Elements. II. Seventeen Trace Elements in Four New Jersey Communities (1972). EPA 600/1-78-37b

Technical Standard Operating Procedures ISSI Consulting Group, Inc. Contract No. N00174-99-D-003

SOP No. ISSI-VBI70-14 Revision No.: 1

Date: 3/2000

TECHNICAL STANDARD OPERATING PROCEDURE HAIR SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

ATTACHMENT 1

Analysis Requisition form (example) Biological Sample Logbook sheet

ANALYSIS REQUISITION

\$ 777

National Medical Services, Inc. 3701 Welsh Rd. • P.O. Box 433A
Willow Grove, Pennsylvania 19090-0437 (215) 657-4900 (800) 522-6671 FAX: (215) 657-2972

CONTROL NO.

519924



ACCOUNT NO.

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| T Ret | FORENSIC CAREARPER TO SER SPECIMEN TY STAT UNIT CIMEN SPECIMEN TY SPECIMEN TY | RVICES DIRECTORY FOR FORENSIC CASE HANDLING INSTRUCT | IONS Date: Crise: If Unite: Bandon: Same Jame: JASS Avolume: ISSUED: Avolume: JASS Avolume: JASS | ACCOUNT INFORMATION: (Fig. shall) of patient medications |
| C254 C 7 X 0460 X 0541 | | DRIV OF SERVICES OR CALL LAB: FOR ADI 1858 DRUG SCREEN & ALCOHOL (BLOOD OR SERUM) 1864 DRUG SCREEN (BLOOD OR SERUM) 8489 FENTANYL + METAB. (FORENSIC) 9315 FLUNITRAZEPAM & METABOLITE | DITIONAL ANALYSES | CONTROL NUMBER 519924 NMS - WILLOW GROVE 19090-0437 |
| 0620 0803 5 0 5 | BENZTROPINE (COGENTIN®) BUPROPION (WELLBUTRIN®)* BUSPIRONE (BUSPAR®) CADMIUM BIOUPTAKE (BLOOD) CADMIUM PANEL (OSHA) | 2134 FORMIC ACID 2143 GABAPENTIN 2152 GHB (GAMMA-HYDROXYBUTYRIC ACID)) 2321 HYDROCARBON + OXYGENATED VOLATILES | 3445 PESTICIDE/INSECTICIDE SCREEN* 3784 POTASSIUM 3976 PROPAFENONE 4105 RISPERIDONE + METABOLITE 4180 SELENIUM | CONTROL NUMBER 519924 |

CONTROL NUMBER

519924



NMS - WILLOW GROVE 19090-0437

CONTROL NUMBER

519924



NMS - WILLOW GROVE 19090-0437

0 (S) CANNABINOIDS (THC) W/ GC/MS 2416 INHALANTS - URINE METABS. 4195 SERTRALINE 2440 CARBAMAZEPINE + METABOLITE ISONIAZID*† 4205 SINEMET®* 2484 LAMOTRIGINE (LAMICTAL®) 3971 CARBAMAZEPINE + METAB. - FREE 0641 SOTALOL CARBAMAZEPINE + METAB. - FREE/BOUND 2492 LEAD - SERUM 4260 SULFONYLUREA HYPOGLYCEMICS CHOLINESTERASE (RBC OR PLASMA) 6020 LEAD IN BLOOD 4305 TACRINE (COGNEX®) CHROMIUM 2541 LSD SCREENT 4370 THALLIUM CLOMIPRAMINE AND METAB. 2551 MAGNESIUM 4395 TICLOPIDINE (TICLID®)* CLONIDINE 2570 MANGANESE 4518 TOPIRAMATE (SERUM OR PLASMA) CLOZAPINE + METABOLITE 2670 MERCURY 4660 TRIFLUOPERAZINE (STELAZINE®) COCAINE + METAB. W/ GC/MS 6153 METALS PANEL - RBC's 4769 VENLAFAXINE + METABOLITE (EFFEXOR*) COPPER 2661 METALS/METALLOIDS I (BLOOD) 4774 VIGABATRIN COTININE - URINE 3020 METHYLPHENIDATE (RITALIN[®])* 4800 WARFARIN DILTIAZEM 3145 NEFAZODONE 4844 数 ZINC ROZEN; SRECIMEN: REQUIRED: TELIGHT PROTECTION REQUIRED

| SECONACTIONS OF SEMMICES FOR SPECIAL MAILING INSTRUCTIONS |
|---|
| IF ANALYSIS DOES NOT APPEAR ABOVE, PLEASE WRITE TEST NAME/NUMBER IN SPACE PROVIDED BELOW. |
| St #1348: Creatinine in linne |
| 25+ # 0460: Hair segmentation required: |
| - 4 segments: 0-1 cm |
| 1-3 cm |
| 3-5 cm |
| (ia) 5-7cm |
| (if length of sample allows) |

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| BLV | WV | YV | CV | RV | BV | LBLV | NB | WPC | BLPC | RPC | |
| BRV | GV | LV | BRPC | | VERIFIC | CATION: | | | | | |

Data Collection Log

| C | Date | Ha | air | | | | Blood | | ine | Comments | |
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| Logbook Page Reviewed By: | Date: |
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TECHNICAL STANDARD OPERATING PROCEDURE HAIR SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

ATTACHMENT 2

Patient names to be used for blind quality control samples

Patient Names to be Used for Blind Quality Control Samples

| Name | Social Security # |
|-------------------------------|----------------------------|
| Kyle Anderson | 527-55-3942 |
| Harold Brame | 304-77-9165 |
| Rajeev Chaula | 636-73-6452 |
| Polly Davis | 746-01-4495 |
| Craig Ensley | 430-67-2533 |
| Alessandro Fortin | 271-85-9411 |
| Abel Glardon | 401-77-1802 |
| Floyd Harrison | 629-54-4980 |
| Robert Hendrickson | 520-11-9257 |
| Andrew Iverson | 410-56-3309 |
| Diana Isham | 461-98-0835 |
| Sarah Jennigan | 529-57-0640 |
| Raymond Jones | 528-62-8117 |
| Frank Knotts | 825-24-1955 |
| James Kutsko | 539-30-9609 |
| Lonnie Labriola | 674-78-0370 |
| Brian Lucero | 665-07-7231 |
| Kristine Molinari | 455-14-8527 |
| Anita Marshali | 347-53-7037 |
| Albert Musser | 936-83-5385 |
| Amy Noel | |
| Etsuko Nishimura | 495-90-0510 |
| Andrew Ochoa | 662-88-3825 |
| | 652-97-6791 |
| Carol Ottmer | 520-92-0424 |
| Beulah Peek | 261-14-4322 |
| Ardith Pritchard | 566-59-2501 |
| Roy Quinlan | 510-50-6497 |
| Agustin Quintero | 427-74-0676 |
| Ace Ratcliff | 512-26-3959 450-42-3918 |
| Aaron Roybal Arturo Sigala | 603-31-3864 |
| Karl Steinbeck | 548-30-5794 |
| Anita Sanchez | 599-10-4556 |
| | 416-61-3547 |
| Kurt Swingle Lao Tizer | 334-30-4184 |
| | |
| Carrie Trupiano | 605-63-4911 |
| Murray Unell | 655-91-6413 |
| Chris Utz | 524-52-0927 |
| Benito Valdez | 520-97-3678 |
| Alvin Voight | 527-21-9696 |
| Barbara Waldinger | 608-93-5468 |
| Peter Wolfe | 568-62-2315 |
| Chong Yang | 520-70-1753 |
| Robert York | 783-14-9328 |
| Byron Johnson | 680-79-8106 |
| Heidi Ham | 500-83-3425 |
| Tim Curran | 512-94-9847 |
| Rebecca Utrup | 352-07-7360 |

| Date: November 30, 19 | 999 (Rev. # 0) | SOP No. <u>ISSI-VB170- 15</u> |
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| | LECTION FOR THE DETERMINATION TO ARSENIC | ON OF RISK-BASED |
| APPROVALS: | | |
| Author | ISSI Consulting Group, Inc. | Date: November 30, 1999 |
| | dardized method for the collection of frisk-based exposure to arsenic. Proto are provided. | |
| Received by QA Unit: | | |
| REVIEWS: | | |
| TEAM MEMBER | SIGNATURE/TITLE | DATE |
| EPA Region 8 | Buth Jack ARM | 2/11/10 |
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| Revision Date | Reason for Rev | vision |
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Technical Standard Operating Procedures ISSI Consulting Group, Inc. Contract No. N00174-99-D-003

SOP No. <u>ISSI-VB170-15</u> Revision No.: 0 Date: 11/1999

URINE SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to provide a standardized method for collecting urine for subsequent determination of exposure to arsenic by residents. Urine samples from participating residents will be collected at a neighborhood clinic by study personnel, using the procedures described in this Standard Operating Procedure (SOP). All personnel involved with urine collection will be trained in this procedure prior to any sample collection. This SOP describes the equipment and operations used for collecting urine, using a procedure that will produce data that can be used to support risk evaluations. Site-specific deviations from the procedures outlined in this document must be approved by the USEPA Region 8 Remedial Project Manager, or Regional Toxicologist prior to initiation of the sampling activity.

2.0 RESPONSIBILITIES

The contractor who is responsible for overseeing the biomonitoring activities (ISSI) will be responsible for checking all work performed and verifying that the work satisfies the specific tasks outlined by this SOP and the Project Plan. It is also the responsibility of the contractor to communicate the need for any deviations from this SOP with the appropriate USEPA Region 8 personnel (Remedial Project Manager, or Regional Toxicologist). It is the responsibility of the subcontractor collecting the sample (Concentra) to communicate with all personnel regarding specific collection objectives and to communicate with ISSI regarding any anticipated situations that require deviation from this SOP.

All personnel performing biological sampling are responsible for adhering to the applicable tasks outlined in this procedure while collecting samples.

3.0 EQUIPMENT

- <u>Collection containers</u> certified arsenic-free, large-mouth sterile collection cup with screw-top lid
- Gloves Disposable, latex, powderless
- Plastic ziplock bags
- Chain-of-Custody forms will be provided by ISSI
- <u>Consent Form</u> will be provided by ISSI
- <u>Field notebook</u> a three-ring binder book that will store necessary forms used to record and track samples collected as part of the VBI70 biomonitoring program. Binders will contain chain-of-custody forms and Data Collection Logsheets.

TECHNICAL STANDARD OPERATING PROCEDURE URINE SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

4.0 COLLECTION OF URINE SAMPLES

Urine samples will be collected from participating residents. Each participant will be directed to the collection facility (Concentra Medical Center). Participating residents will arrive at the collection facility with a voucher provided by ISSI. Concentra personnel will fill out a chain-of-custody form (example provided in Attachment 1) for each sample. All participants will be instructed as to the approved procedure for collecting and submitting urine samples. Samples will be clearly marked with the patient's name, date of collection, and patient's social security number. Each sample must have a sample identification label affixed to the outside of the collection cup, and also affixed to the chain-of-custody form. All samples must be tracked using the field notebook, as described in Section 6.2

Prior to and following urination, each participant must wash their hands.

Urine samples will be collected by taking the wide mouthed bottle into the bathroom. Start to urinate into the toilet as you normally do. After urination has started, collect the sample by intercepting the urine stream in mid-air with the wide-mouth bottle. Fill the bottle at least half full with urine and stop collection by moving the bottle out of the urine stream.

Children should be accompanied by their parent or guardian into the bathroom and their sample should be collected by an adult. Adults and teenagers may use the same sample collection techniques as children, but do not require assistance in sample collection.

Following collection, the container lid must be tightly secured.

5.0 SAMPLE CONTAINERS AND LABELING

Following the procedures outlined in Section 4.0, samples will be collected directly into sample containers and labeled with a unique sample identification number. Each sample must have a sample identification number affixed to the collection cup, and also attached to the chain-of-custody form.

6.0 FIELD QUALITY ASSURANCE/QUALITY CONTROL

Adherence to quality assurance/quality control (QA/QC) procedures is an important part of field sample collection. Field QA/QC procedures include documentation requirements and preparation of field QC samples.

6.1 Field Quality Assurance Samples

The following quality control samples will be collected during this project to help assess the

Technical Standard Operating Procedures ISSI Consulting Group, Inc. Contract No. N00174-99-D-003

SOP No. <u>ISSI-VBI70-15</u> Revision No.: 0 Date: 11/1999

URINE SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

precision and accuracy of the data collected. All quality control samples will be inserted into the sample stream by ISSI.

Field Duplicate: Field duplicate samples are collected at the same time as the primary sample, and are submitted blind to the analytical laboratory to test both the precision of the analysis and the precision of sample collection. In this case, the field duplicate sample is a second sample of urine collected from the same individual. This sample will be collected by filling a second cup immediately following the first cup. A minimum of 3 field duplicates will be collected from participating adults. If the number of participants exceeds 50, field duplicate samples will be collected at a frequency of 5% of all samples collected (1 field duplicate per 20 investigation samples collected). Field duplicate samples are submitted in a blind fashion to the analytical laboratory. In order to maintain anonymity, field duplicates will be labeled with 'dummy' patient names and inserted into the sample stream. A list of 'dummy' patient names is provided in Attachment 2. Direction and submission of field duplicates will be the responsibility of ISSI.

<u>Blind Standard</u>: The accuracy of an analytical method is evaluated by analyzing a sample medium fortified with a known concentration of target analytes that has been certified using the preparation and analysis method for that particular sample medium. Blind standards will be inserted into the sample stream using 'dummy' patient names to maintain the anonymity of the sample. A minimum of 3 blind standards at 2 arsenic concentrations will be inserted into the sample stream by ISSI.

6.2 Field documentation

A field notebook should be maintained by the personnel collecting blood samples. The field notebook is a three-ring binder that contains a Data Collection Log and the Analysis Requisition form for each patient. All entries in the field logbook must be signed and dated by the person recording the information.

The following information will be included on the Data Collection Log:

- date of collection
- time of collection
- name of sampling technician
- patient name
- patient's social security number
- descriptions of any deviations to this SOP and the reason for the deviation

An example of the Analysis Requisition form and the Data Collection Log is provided in Attachment 1.

URINE SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

7.0 DECONTAMINATION

Biological sampling equipment will not be re-used. All sampling equipment must be disposed in the appropriate container(s).

8.0 GLOSSARY

<u>Project Plan</u> - The written document that spells out the detailed site-specific procedures to be followed by the Project Leader and the Clinic Personnel.

9.0 REFERENCES

Agency for Toxic Substances and Disease Registry, 1998. Exposure Investigation, Milltown Reservoir Sediments National Priorities List Site, Clark Fork River Operable Unit, Deer Lodge, Powell County Montana, U.S. Department for Health and Human Services.

URINE SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

ATTACHMENT 1

| | · | | | | EQUISITION | | | |
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Data Collection Log

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TECHNICAL STANDARD OPERATING PROCEDURE URINE SAMPLING FOR THE DETERMINATION OF RISK-BASED EXPOSURE TO ARSENIC

ATTACHMENT 2

Patient Names to be Used for Blind Quality Control Samples

| Name | Social Security # |
|--------------------|-------------------|
| Kyle Anderson | 527-55-3942 |
| Harold Brame | 304-77-9165 |
| Rajeev Chaula | 636-73-6452 |
| Polly Davis | 746-01-4495 |
| Craig Ensley | 430-67-2533 |
| Alessandro Fortin | 271-85-9411 |
| Abel Glardon | 401-77-1802 |
| Floyd Harrison | 629-54-4980 |
| Robert Hendrickson | 520-11-9257 |
| Andrew Iverson | 410-56-3309 |
| Diana Isham | 461-98-0835 |
| Sarah Jennigan | 529-57-0640 |
| Raymond Jones | 528-62-8117 |
| Frank Knotts | 825-24-1955 |
| James Kutsko | 539-30-9609 |
| Lonnie Labriola | 674-78-0370 |
| Brian Lucero | 665-07-7231 |
| Kristine Molinari | 455-14-8527 |
| Anita Marshall | 347-53-7037 |
| Albert Musser | 936-83-5385 |
| Amy Noel | 495-90-0510 |
| Etsuko Nishimura | 662-88-3825 |
| Andrew Ochoa | 652-97-6791 |
| Carol Oitmer | 520-92-0424 |
| Beulah Peek | 261-14-4322 |
| Ardith Pritchard | 566-59-2501 |
| Roy Quinlan | 510-50-6497 |
| Agustin Quintero | 427-74-0676 |
| Ace Ratcliff | 512-26-3959 |
| Aaron Floybal | 450-42-3918 |
| Arturo Sigala | 603-31-3864 |
| Karl Steinbeck | 548-30-5794 |
| Anita Sanchez | 599-10-4556 |
| Kurt Swingle | 416-61-3547 |
| Lao Tizer | 334-30-4184 |
| Carrie Trupiano | 605-63-4911 |
| Murray Unell | 655-91-6413 |
| Chris Litz | 524-52-0927 |
| Benito Valdez | 520-97-3678 |
| Alvin Voight | 527-21-9696 |
| Barbara Waldinger | 608-93-5468 |
| Peter V /olfe | 568-62-2315 |
| Chong Yang | 520-70-1753 |
| Robert York | 783-14-9328 |
| Byron Johnson | 680-79-8106 |
| Heidi Ham | 500-83-3425 |
| Tim Curran | 512-94-9847 |
| Rebecca Utrup | 352-07-7360 |
| Tropecois Offith | 332-01-1300 |

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| VB170 Biomonitoring Sampling and Analysis Plan | | | |
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| Preparation and Analysis Methods for Urir | r Lead in Blood, Total ne, and Creatinine in U | Arsenic in Hair, In Jrine | organic Arsenic in |
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Toxicology Specialists Worldwide Since 1970

3701 Welsh Road Willow Grove, PA 19090 Phone: (215) 657-4900

1-800-522-6671 Pax: (215) 657-2972

NAME OF TEST:

LEAD in Blood Analysis
by Graphite Furnace Atomic Absorption Spectrometry

NMS # 6020

ANALYTE CLASSIFICATION:

Heavy Metal

Atomic Number: 82 Atomic Weight: 207.2

Valence: 2, 4

METHOD PRINCIPLE:

Lead in blood is determined using graphite furnace atomic absorption spectrometry. The samples are diluted with chemical modifier and injected directly into the graphite furnace. Concentrations are calculated using a calibration curve constructed from a series of blood standards.

SPECIMEN REQUIREMENTS:

| Blood | 1.0 mL | 0.5 mL | 0.2 mL ' |
|-------|---------------------------------|--------|----------|
| | TISS IN THE PARTY NAMED AND THE | | 1.0 |

SPECIAL HANDLING:

None

1.

REPORTING LIMIT:

1 mcg/dL Blood

PHARMACOTOXICOLOGIC

DATA:

None available

LIMITATIONS OF METHOD:

- Quantitative results cannot exceed the highest working standard for that run.
- 2. There is no known interference for this analysis by GFAAS.

REFERENCES:

- 1. Toxicology and Biological Monitoring of Metals in Humans. Carr, Ellis & Carr. (eds.) pp. 126-135, Lewis Publishers, Chelsea, MT, 1985
- 2. Department of Health, August 20, 1988, Regulations (34 Pa. B. 3697)
- 3. Health & Environment Digest, Lead: Assessing its Health. 2: 1-5, 1988
- 4. Jacobson, B.E., Lockitch G., Quigley, G., Improved Sample Preparation for Accurate Determination of Low Concentrations of Lead in Whole Blood by Graphite Furnace analysis. Clin. Chem. 37: 515-19, 1991.
- 5. Boone, J., Hearn, T., Lewis, S., Comparison of Inter Laboratory Results for Blood Lead with Results from A Definitive Method, Clin. Chem. 25: 389-93, 1979.
- 6. Wang, ST., Peter Fr., The Stability of Human Blood Lead in Storage, J. Anal. Tox. 8: 85-8, 1985.
- 7. Fernandez, F.J., Hilligoss, D., An improved Graphite Furnace Method for the Determination of Lead in Blood Using Matrix Modification and L'vov Platform, At. Spectrosc. 3: 130-1, 1982.

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Mational Medical Services & Itsus



NATIONAL MEDICAL SERVICES NEW TEST ANNOUNCEMENT

TOTAL INORGANIC ARSENIC & METABOLITES (Speciated Arsenic) TEST CODE: 0467

Sources of Exposure

Arsenic is the twentieth most abundant element in the earth's crust and may be found in all living organisms. It may be present in soil, food, shellfish, tobacco, coal dust and well water. The daily diet in the United States contains below 0.04 mg of arsenic but may contain up to 0.2 mg per day if the diet contains seafood. Individuals may be exposed to a number of different forms of arsenic from the environment and/or from their occupation. These different forms of arsenic have varying toxicities.

Non-toxic forms of arsenic include arsenocholine and arsenobetaine which are present in seafood and are commonly referred to as seafood or organic arsenic. Together they can reach levels exceeding 1000 mcg/mL urine within 1-2 days following a single meal of fish or shellfish.

The forms of arsenic which are toxic are collectively termed inorganic arsenic and methylated metabolites. These toxic forms of arsenic include trivalent arsenic, pentavalent arsenic, dimethylarsinic acid and methylarsonic acid, and are commonly referred to as total inorganic arsenic, non-dietary arsenic or speciated arsenic. Inorganic arsenic can be found in hazardous waste sites, pesticides, herbicides, glassware, marine paints, ant pastes and veterinary antihelminths. Inorganic (or non-dietary) arsenic is also involved in alloy production, pigment production, microchip production, and the smelting of copper, lead and zinc. The greatest source of human exposure today is through the use of arsenical pesticides, which accounts for over 80% of industrial arsenic exposure. Arsenic can be absorbed into the body following inhalation, ingestion or dermal contact.

Health Effects

Assessing chronic exposure to the toxic forms of arsenic (inorganic or non-dietary arsenic) may be difficult since the symptoms tend to be nonspecific. These symptoms usually involve diarrhea, abdominal pain, hyperpigmentation of the skin and dermal lesions. There may be localized edema, sore throat, salivation, garlic odor of the breath, cardiovascular and/or neurological effects. There is also epidemiological evidence suggesting a significant increase in the incidence of skin and lung cancer. Symptoms of acute exposure to inorganic arsenic may include nausea, vomiting, chest pain, cerebral edema, delirium, coma and death.

Laboratory Test Indications - Biologic Monitoring:

The American Conference of Governmental Industrial Hygienists (ACGIH) recommends monitoring workers exposed to arsenic by collecting and analyzing the end of the work week urine for total inorganic arsenic (Test Code 0467).

Total arsenic analysis (Test Code 0466) measures both inorganic and organic arsenic. This test can be used to monitor workers if the workers avoid seafood for at least two days prior to specimen collection. However, it is often difficult to control seafood intake prior to specimen collection. If an elevated result is obtained using this test, it is recommended that the urine is analyzed for total inorganic arsenic to determine whether the exposure is related to dietary or non-dietary arsenic.

Total Arsenic analysis (Test Code 0460) is more appropriate in blood, serum, plasma or

other tissues in cases of suspected poisoning or overexposure.

In addition to the above mentioned tests, our Hair Exposure analysis for Arsenic is appropriate for determining past exposure to arsenic (i.e. more than 7 days). Sometimes it is important to determine the time frame of arsenic poisoning. Segmentation of the hair can be performed to determine the approximate time of exposure. Please call the laboratory for segmentation fees, or for total inorganic (non-dietary) arsenic analysis in specimens other than urine.

| Test Name: | Total Inorganic Arsenic, Urine (Speciated) | Total Arsenic, Urine | Arsenic, Serum, Plasma, Blood | Total Arsenic, Hair |
|---------------------------|---|---|--|---|
| Test Code: | 0467 | 0466 | 0460 | 0460 |
| Specimen Requirements: | Week Urine | 10 mL End of work Week Urine. Avoid seafood consumption for 48 hours prior to sample collection. | performed using a royal blue top tube.) | at roots, and indicate root end if segmentation analysis is required. |
| Method of Analysis: | | Graphite Furnace Atomic Absorption Spectroscopy | Graphite Furnace Atomic Absorption Spectroscopy | Graphite Furnace Atomic Absorption Spectroscopy |
| Reporting Limit: | 10 mcg/L | 20 mcg/L | 5 mcg/L | Depends on weight of hair submitted. |
| Range: | Range (unexposed population): less than 20 mcg/L. Biological Exposure Index (BEI): 00 mcg/g creatinine. | (unexposed population): less than 20 mcg/L. Seafood consumption within 2 to 3 days before specimen collection can markedly increase total arsenic evels. Biological Exposure Index BEI): 50 mcg/g creatinine. | (unexposed normal): less than 5 mcg/L. Seafood consumption within 2 to 3 days before specimen collection can markedly increase total arsenic levels. | analysis. Usually 0:03 to 3 mcg/g hair. |
| References: | I. ACGIH | American Confer | ence of Govern | nmental |

| Industrial Hygienists. Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. Cincinnati, 1991 - 1992. 2. Vahter, M., Clin. Chem., 40, 678-80, 1994. 3. Baselt, R.C., Cravey, R.H., Disposition of Toxic Drugs and Chemicals in Man, 3rd Edition, 65 - 69, 1989. | |
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For more information concerning Arsenic or other analyses, please call 800-522-6671.

- ► NMS HOME PAGE
 ► Featured Tests
- ► Alphabetical Test Listing

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3701 Weish Road Willow Grove, PA 19090 Phone: (215) 657-4900

1-800-522-6671 1-800-522-6671 Pasc: (215) 657-2972

NAME OF TEST:

ARSENIC in Dialysis Water, Digested Sample, Liquid

NMS # 0460

by Graphite Furnace

Atomic Absorption Spectrometry

ANALYTE CLASSIFICATION:

Metalloid

Atomic Number: 33 Atomic Weight: 74.92

Valence: 3,5

METHOD PRINCIPLE:

Graphite furnace atomic absorption spectrometry (GFAAS) is an atomic absorption technique which uses the characteristic wavelength absorbed from ground-state atoms of an analyte to determine trace metal concentrations. Zeeman background correction is employed in this method. Samples are injected directly into the graphite furnace with nickel nitrate chemical modifier. The Concentrations are calculated by the computer system using a calibration curve based on aqueous standards.

SPECIMEN REQUIREMENTS:

| Liquid | 1.0 ML | 0.5 ML | 0.25 mL |
|-----------------|------------------------|--|---------|
| Dialysis Water | 2.0 mL | 0.5 mL | 0.25 mL |
| Tissue | 0.5 g | 0.1 g | 0.03 g |
| Hair | 0.5 g | 0.1 g | 0.03 g |
| Nail | 0.5 g | 0.1 g | 0.03 g |
| SPACE OF STREET | TISBUELS DIMBILLIDACIO | STATE OF STA | |

REPORTING LIMIT:

5 mcg/L for Dialysis Water, Liquid

Determined for each analysis for Dinested Samples

PHARMACOTOXICOLOGIC DATA:

Current data is available in the laboratory computer system and on each individual patient report.

LIMITATIONS OF METHOD:

- Quantitative results cannot exceed the highest working standard for that run.
- There is no known interference for As analysis by GFAAS.

REFERENCES:

- 1. Paschal DC, Kimberly, MM, and Balley, GG. Determination of Urinary Arsenic by Electrothermal Atomic Absorption with the L'vov Platform and Matrix Modification. Anal. Chimica Acta, pp. 179-186, (1980). (See NMS Tech File Database Doc. #2926)
- Schlemmer, G and Welz B. Palladium and Magnesium Nitrates, a More Universal Modifier for Graphite Furnace Atomic Absorption Spectrometry, Spectrochimica Acta, 41B, 1157-65 (1986).
- 3. Dlx, K, et al. Arsenic Speciation by Capillary Gas-Liquid Chromatography, J. Chrom. Sci., 25, 164-169 (1987).

- 4. Foa, V. et al, The Speciation of the Chemical Forms of Arsenic in the Biological Monitoring of Exposure to Inorganic Arsenic, The Sci. of the Total Envir., 34, 241-259 (1984).
- 5. Yamauchi, H., et al, Biological Monitoring of Arsenic Exposure to Gallium Arsenide and Inorganic Arsenic Exposed workers by Determination of Inorganic Arsenic and its metabolites in Urine and Hair, Am. Ind. Hyg. Assoc. J., 50, 606-12 (1989).
- 6. Versieck, J. and Cornelis, R., Trace Elements in Human Plasma of Serum, CRC Press (Boca Raton, Florida), p. 75 (1989).
- 7. Lauwery, R.R., Industrial Chemical Exposure: Guidelines for Biological Monitoring, Biomedical Publications (Dans, CA), p. 47 (1983).
- 8. Accumulated NMS data, 1990.

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Pax: (215) 657-2972

NAME OF TEST:

TOTAL INORGANIC (NON-DIETARY) ARSENIC IN URINE by Hydride Generation

NMS #.0467

ANALYTE CLASSIFICATION:

Metalloid

Atomic Number:33 Atomic Weight: 74.92 3.5

Valence:

METHOD PRINCIPLE:

The hydride technique involves the reaction of acidified aqueous samples with a reducing agent, such as sodium borohydride. The sodium borohydride/acid reduction generates hydrides as shown in the follow equations (1).

NaBH4+3H20+HClOH3BO3+NaCL+8H

Em+ +H(excess)ÖEHn+H2(excess) [Eq.2]

where E = the analyte of interest and m may or may not equal n.

This reaction generates a volatile hydride which is transported to a quartz cell by means of an argon carrier gas. In the quartz cell, the hydrides are converted to gaseous metal atoms.

It is believed that atomization of the hydride occurs from collisions with free hydrogen radicals (2,3). In the quartz cell, the generated analyte atoms are contained in the path of a source lamp and a signal is generated by measuring the amount of light absorbed.

These signals can then be used to determine trace metal concentrations. Aqueous spiked standards and urine samples are first mixed with pre-reducing solution, and then sampled to a hydride generator through a flow injection analyzer. The concentrations are calculated by using the calibration curve based on aqueous spiked standards.

SPECIMEN REQUIREMENTS:

| Dialysis Water | 5.0 mL | 2.0 mL | 0.25 mL |
|----------------|--------|--------|---------|
| Urine | 5.0 mL | 2.0 mL | 0.25 mL |
| | | | |
| | | | |

REPORTING LIMIT:

10 mcg/L

LIMITATIONS OF METHOD:

- Quantitative results cannot exceed the highest working standard or be less than the lowest working standard for that run.
- 2. There are no known interferences for Inorganic Arsenic analysis by hydride generation.

PHARMACOTOXIGOLOGIC DATA:

Current data is available in the laboratory computer system and on each individual patient report.

REFERENCES:

- 1. Dix, K., et al. Arsenic Speciation by Capillary Gas-Liquid Chromatography Chrom Sci., 25, 164-169 (1987).
- 2. Foa, V., et al. The Speciation of the Chemical Forms of Arsenic in the Biological Monitoring of Exposure to Inorganic Arsenic. The Sci. of the Total Envir., 34: 241-259 (1984).
- 3. Yamauchi, H., et al. Biological Monitoring of Arsenic Exposure to Gallium Arsenide and Inorganic Arsenic Exposed workers by Determination of Inorganic Arsenic and its metabolites in Urine and Hair, Am. Ind. Hyg. Assoc. J., 50:606-12 (1989).
- Versieck, J. and Cornelis, R., Trace Elements in Human Plasma of Serum, CRC Press (Boca Raton, Florida), p. 75 (1989).
- 5. Lauwery, R.R., Industrial Chemical Exposure: Guidelines for Biological Monitoring, Biomedical Publications (Dans, CA), p. 47 (1983).
- 6. Accumulated NMS data, 1990.

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NAME OF TEST:

CREATININE

NMS # 1348 TS-608-CRE-01

SYNONYM:

CREAT

ANALYTE CLASSIFICATION:

Urinary constituent

METHOD PRINCIPLE:

This method is a colorimetric determination based upon the reaction of creatinine with picric acid under alkaline conditions. The rate of production of a red color complex measured is proportional to the amount of creatinine present. This analysis is performed on the Instrumentation Laboratory Monarch 2000 Auto-Analyzer.

ALTERNATIVE METHOD:

Abbott TDX Test

SPECIMEN REQUIREMENTS:

SPECIAL HANDLING:

Specimen should be kept refrigerated.

REPORTING LIMIT:

5 mg/L

LIMITATIONS OF METHOD:

Quantitative results cannot exceed the highest working standard or be less than the lowest working standard for that run.

2. There are no known interferences.

PHARMACOTOXICOLOGIC DATA:

Creatinine mg/L

Usually 600 to 2000 mg/day urine

To determine mg/day, multiply mg/L by the number of liters collected in a 24-hour

period.

REFERENCES:

Instrumentation Laboratory package insert Creatinine 35243, issued December,

1991.

Attachment 2

- Letter to Residents
- Clinic Voucher
- Instructions for providing samples
- Informed consent forms
- Fact Sheet



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 8
999 18TH STREET - SUITE 500
DENVER, CO 80202-2466
http://www.epa.gov/region08

Ref: 8EPR-SR

Dear Resident:

As you know, the Environmental Protection Agency (EPA) collected soil samples from your yard as part of a study in your neighborhood to identify homes that may have elevated levels of arsenic or lead in soil. The results of the sampling of your yard indicate that a clean up is needed. With your cooperation, EPA will do the necessary cleanup at no cost to you.

In this period of time before EPA begins the cleanup of your yard, we wish to be sure that you and your family members are not being exposed to unsafe levels of arsenic or lead from the soil. The best way to do this is to measure the levels of arsenic in your urine and/or hair, and the level of lead in your blood. I encourage you and all the members of your family to volunteer to have these measurements taken. If any of the samples indicate higher than normal levels, I or another EPA representative will immediately meet with you to identify ways to reduce the exposures to safe levels. EPA may publish summaries of the measurements but your name and individual results will be kept strictly confidential.

If you choose to have the measurements taken, you will need to go to the Concentra Medical Center on 58th Street so that the required samples can be collected by a trained health technician. A map showing the location of the clinic is attached. EPA is offering this as a service to you and your family members and there is no cost to you. For each member of your family, all you need to do is fill out the attached form with their name and address and take the form and the enclosed voucher to the clinic. I will provide the results of the analyses to you as soon as they are reported to EPA.

If you have any questions about any part of this offer, don't hesitate to call me at (303) 312-6579, Ted Fellman at (303) 312-6119, or Patricia Courtney at (303) 312-6631.

Sincerely,

Bonnie Lavelle

Remedial Project Manager

AUTHORIZATION FOR PARTICIPATION CLINIC VOUCHER

Project: ISSI Consulting Group, Inc. - VB-I70

| Name: | | |
|----------|------|--|
| Address: | | |

Tests

- 1. Urine Arsenic
- 2. Hair Arsenic
- 3. Blood Lead

Authorized By: Ponila

EPA

Date: 2/15/00

Note: This voucher is valid through Saturday, March 31, 2000.

Clinic Location

CONCENTRA MEDICAL CENTERS

CONCENTRA NORTH 420 E. 58th Ave., Suite 111 Denver, CO 80216 (303) 292-2273

Hours: 7 a.m. - 6 p.m. (Walk-in, No appointment required)

Directions: Take I-25 to 58th St. Go east on 58th. The clinic is directly east of Wendy's.

I-25

58th

WENDYS

*CLINIC

How samples are collected:

<u>Blood:</u> About 2 tablespoons of blood will be drawn from each person who volunteers to participate in this study.

<u>Urine:</u> You will be given a collection cup, and asked to provide about 3 ounces of urine. You should avoid seafood and red wine for three days before you go.

Hair: A small bundle of hair (about the width of a pencil) will be collected from an inconspicuous place (back of the neck or behind the ears).

CONSENT TO PARTICIPATE IN BIOMONITORING

Before agreeing that I will participate in this study, it is important that I read and understand the following explanation. It describes, in words that can be understood by a lay person, the purpose, procedures, benefits, risks and discomforts of the study and the precautions that will be taken. It also describes the alternatives available and the right to withdraw from the study at any time. It is important to understand that no guarantee or assurance can be made as to the results of the study. It is also understood that participation in this study is strictly voluntary and that refusal to participate in whole or any portion of the study will not result in penalty to me or my family, or influence the availability of standard medical treatment.

| I, | have volunteered to participate in the |
|-----------------------|--|
| biomonitoring p | program in my neighborhood. |
| | nd that by volunteering, I will receive information about the level of d and/or the level of arsenic in my hair and/or urine. |
| | OR |
| I, my family for b | wish to volunteer the following members of lood lead, urinary arsenic and/or hair arsenic testing: |
| | , age |
| | nd that by volunteering, I will receive information about the level of d/or arsenic in hair and/or urine in each member of my family who |
| Procedures | |

| I understand that my voluntary participation in this biomonitoring program will involve some temporary inconvenience. I understand that I will be asked to go to a neighborhood location so that some blood, urine and/or hair can be collected from myself or members of my family. |
|--|
| I understand that I will not receive any compensation for my participation. |
| I, voluntarily agree to have the following samples collected as part of the biomonitoring program and consent to participation |
| My participation involves (indicate which samples you would like to have collected): |
| Yes No urine (arsenic test). Allowing collection of about 3-4 oz. of urine. |
| hair (arsenic test). Allowing collection of a small amount of hair (approximately as wide as a pencil) from an area on the head in a minimally conspicuous area. |
| blood (lead test). Allowing collection of about 1-2 teaspoons of blood. |
| Potential Benefits |
| I understand that this study may benefit me because it may help me to determine if myself or members of my family are being exposed to excess levels of lead or arsenic, and may help me find ways to reduce these exposures. |
| Risks, Discomforts and Precautions |
| I understand that collection of blood requires that a small needle be used to enter a vein. I also understand that a bruise can develop at the site where blood is drawn. |
| I understand that collection of urine will require me to urinate into a collection container at the laboratory. |
| I understand that collection of hair requires that a small amount of hair be collected from near my scalp. The amount of hair will be approximately the width of a pencil. The location for the collection will be selected in a minimally |

conspicuous area.

Confidentiality of Records

I understand that personal information will be kept in confidence by the biomonitoring staff. I also understand that neither I, nor any member of my family, will be identified by name in any reports of the results of the program.

I understand that I can obtain additional information about this program and my rights by contacting Bonnie Lavelle, at (303)-312-6579, or the following address:

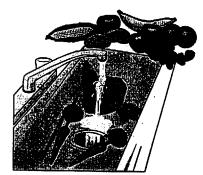
U.S. Environmental Protection Agency 999 18th Street, Suite 500 Denver, Colorado 80202

I understand that I have the right to withdraw from having my blood, urine, or hair tested at any time and that withdrawing will not result in any penalty to me.

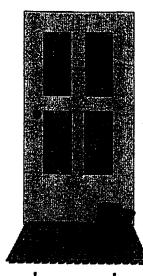
Based on the information provided above and having had the opportunity to discuss any concerns with the investigator or his designee, I voluntarily consent to participate in this biomonitoring program.

| Printed Name of Volunteer (Or name of Parent or Guardian if form is Being signed for a minor) | Signature of Volunteer | |
|---|------------------------|--|
| | | |
| Name of Witness (Printed) | Signature of Witness | |
| | Date | |

Ways to protect your health By keeping dirt from getting into your house and into your body



Wash and peel all fruits, vegetables, and root crops



Wipe shoes on doormat or remove shoes



Don't eat food, chew gum, or smoke when working in the yard



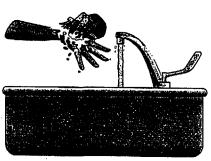
Damp mop floors and damp dust counters and furniture regularly



Wash dogs regularly

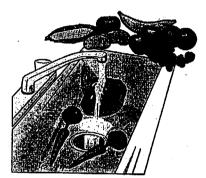


Wash children's toys regularly

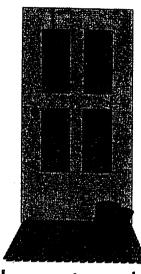


Wash children's hands and feet after they have been playing outside

Cómo proteger su salud Evitando que el polvo entre a su casa o a su cuerpo



Limpie y pele las frutas, los vegetales y las viandas



Limpiese los zapatos en la alfombra de la entrada o quitese los zapatos



No coma, mastique goma de mascar, o fume mientras esté trabajando en el patio



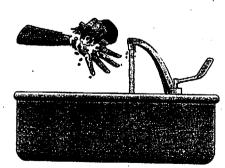
Limpie la casa con año y trapeador húmedo



Bañe a los perros regularmente



Limpie regularmente los juguetes de los niños



Lave las manos y los pies de sus niños después de que hayan estado jugando afuera